APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

	Application No.	Applicant(s)
	09/881,234	BLAIR ET AL.
Office Action Summary	Examiner	Art Unit
	Carolyn L Smith	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>25 November 2002</u> .

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

        1.☐ Certified copies of the priority documents have been received.

        2.☐ Certified copies of the priority documents have been received in Application No. _____ .

        3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

    a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .

4)☐ Interview Summary (PTO-413) Paper No(s). _____ .

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: .

DETAILED ACTION

Applicants' election with traverse of specie A (data elements which contain polynucleotide sequences) in Paper No. 3, filed 11/25/02, is acknowledged.

Applicants' traversal is on the grounds that the specie election requirement is improper under MPEP 803.02, primarily that the Markush group members are "sufficiently few in number" so as not to warrant a specie election.

The applicants' request to remove the specie election requirement was found unpersuasive because of the following reasons (summarized from the restriction paper):

The distinctness or independence of a polynucleotide versus a polypeptide is because they are directed to different chemical types. The completely separate chemical and entity types of these species are often separately characterized and published in literature, thus adding to the search burden if both species were examined together, regardless of how many species are in the Markush group. Also, processing that may connect these species does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the species are independent and distnct invention types for restriction purposes.

The requirements are still deemed proper and are therefore made FINAL.

The corrected drawings, filed on 11/25/02, have been approved by the draftsperson.

Claims herein under examination are 1-23.

Specification

The disclosure is objected to because of the following informality: "suject" is misspelled on page 18, line 16. Appropriate correction is required.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1 (lines 8, 15, and 17-20), 5 (line 2), 6 (line 1), 13 (lines 2-4, 11, 18, 20-21, 23-24, and 26), 17 (line 2), 18 (line 2) are vague and indefinite due to the unclarity of citing the abbreviation CPU. Correction is suggested by amending in of the full name in parentheses. Claims 2-4, 7-12, 14-16, and 19-23 are also rejected due to their direct or indirect dependence from claims 1, 6, 13, and 18.

Claims 1 (line 12) and 13 (line 15) are vague and indefinite due to the unclarity of citing the abbreviation ID. Correction is suggested by amending in of the full name in parentheses. Claims 2-12 and 14-23 are also rejected due to their direct or indirect dependence from claims 1 and 13.

Claims 4 (line 4) and claim 16 (line 4), recite the phrase "efficient structure" which is vague and indefinite. It is unclear what criteria or to what degree one considers the structure to

be efficient. Clarification of the metes and bounds of this phrase via clearer claim wording is requested.

Claims 7 (line 7) and 19 (line 8), recite the word "efficiently encoded representation of alignment" which is vague and indefinite. It is unclear what criteria or to what degree one considers the representation of alignment to be efficiently encoded. Clarification of the metes and bounds of this phrase via clearer claim wording is requested. Claims 8-11 and 20-22 are also rejected due to their direct or indirect dependence from claims 7 and 19.

Claims 8 (line 2), 10 (line 1), 11 (line 2), 21 (line 2), and 22 (line 2) are vague and indefinite due to the unclarity of citing the abbreviation BLAST. Correction is suggested by amending in of the full name in parentheses.

Claim 8, line 1-2, recites the phrase "seed point and sum-set membership" which is vague and indefinite. It is unclear how the Applicants intend this phrase to be defined. Clarification of the meaning of this phrase is requested.

Claims 12 (line 2) and 23 (line 2) contain embodiments which are beyond the elected invention, particularly "proteomic databases." Correction is suggested by stating only the embodiments (in this case "genomic databases") which are part of the invention.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. (e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 6-7, 9-10, 12-13, 16, 18-21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altschul et al. (1990), in view of Fujimiya et al. (P/N 5,706,498), Anderson et al. (1998), Lincoln et al. (P/N 6,303,297), and Matsumoto et al. (2000).

Altschul et al. (1990) disclose an algorithm named BLAST which performs DNA sequence comparisons on the computer in a variety of contexts, including DNA database searches (page 403, abstract, lines 1 and 5-8). Altschul et al. disclose searching newly sequenced genes (query dataset) to DNA sequence databases (subject dataset) (page 403, col. 1, lines 4-8). Altschul et al. disclose the sequence segments can be of any length (page 404, col. 1, lines 34-36) or certain short sequences thus having a specified range (page 404, col. 2, lines 61-63). Altschul et al. use a list, or index, of all 12-mers in a query sequence in one example (page 405, col. 1, lines 33-35). Altschul et al. disclose a word pair to be a segment pair of fixed length, w, (page 404, col. 2, lines 25-26) and determine the number of 12,500 word combinations by multiplying 50 words by 250 (page 404, col. 2, lines 55-57). Altschul et al. disclose compressing

the database by packing 4 nucleotides into a single byte and using a table to delimit the boundaries between adjacent sequences (page 405, col. 1, lines 37-40). Altschul et al. disclose filtering out "uninformative" words or subsequences from the query list which including repeats (page 405, col. 1, lines 61-69). Altschul et al. disclose creating a table of all the hits or comparisons of w-mers in the database (page 405, col. 2, lines 16-19). Altschul et al. disclose two gene datasets (page 409, col. 1, lines 9-11) which were run in BLAST using various comparison parameters, such as match score 5, mismatch score –4, and w=12 (page 409, col. 2, lines 3-5). Altschul et al. do not determine the communication between master and slave CPUs, loop sequences, store start and stop bounds information of sequences and an efficiently encoded alignment representation, including files with sequence data and metadata, or generate a report.

Fujimiya et al. (P/N 5,706,498) disclose M as the number of elements of the first sequence data and N as the number of elements of the second sequence data (col. 4, lines 8-10). Fujimiya et al. disclose the number of computations as M*N (col. 4, line 27 and col. 6, lines 24-26). Fujimiya et al. disclose computing similarity between sequences and subsequences (col. 4, lines 29-36). Fujimiya et al. disclose a workstation involved in a network as well as a database from a research institution or organization (col. 7, lines 59-67). Fujimiya et al. disclose a transfer of data through the network where information from a gene database is acquired, a homology analysis is performed, and results are retrieved (col. 8, lines 8-18).

Anderson et al. (1998) disclose testing a subset of EMBL database (subject dataset) with seed (query) sequences (page 350, col. 2, lines 48-50) and a test set (query dataset) with various lengths (page 351, col. 1, lines and Table 1). These sequences featured lengths within the range of 100 to 1000 bp (page 351, col. 2, lines 3-4). Anderson et al. disclose task definitions which

include comparison parameters, such as parameters and scoring matrix (page 351, Table 2);

executable elements, such as Smith-Waterman and BLAST algorithms (caption of Table 2, page

351); and data element ID/descriptors, such as the gene name and accession numbers (page 351,

Table 2).

Lincoln et al. (P/N 6,303,297) disclose a method and system of storing and retrieving

data from a database and external public databases (col. 3, lines 30-37), which the Examiner

interprets as master and slave CPUs. The data is edited before entry into the system (col. 3, lines

36-37) and stored as information in database tables (col. 3, lines 41-43). Lincoln et al. disclose

the sequence data as well as other annotated biological information can be accessed and stored

(col. 15, lines 46-51 and Figure 17). Lincoln et al. disclose that users can store, track, and

manipulate the sequences with access to an integrated network, including CPUs (col. 15, lines

51-59). The database is stored at a file server connected to the network, with computers linked

to a computer with the internal database, including input and output devices (col. 15, lines 60-

67). Lincoln et al. disclose the sequence comparisons performed involve comparing within

clustered data sets, within the internal database or with external databases (col. 19, lines 34-37).

Lincoln et al. disclose the comparisons are made and match BLAST scores are checked against a

threshold (col. 12, lines 42-48). If the threshold is exceeded then the sequence is annotated with

the appropriate match information and further comparisons are halted (col. 12, lines 48-51),

suggesting that if no threshold is reached then comparisons continue in an iterative or looping

manner. Data relating to the comparisons are stored in tables containing information about the

quality of sequence matches and other features, including homology, and functional motifs and

domains (col. 19, lines 42-54), such as those found in a BLAST report (Figure 6). Figure 6

features index information for both the query and subject (match), line alignments note the start and stop of the sequences, and listed BLAST scores for high-scoring pairs.

Matsumoto et al. disclose DNA sequence compression algorithms for DNA that preprocesses palindrome or repeat sequence which eliminates redundancy (page 43, abstract, lines 15-17), packs each DNA sequence into an efficient structure (less than 2 bits per symbol) (abstract, lines 7-8), creates an index, or context tree, with nodes to store information (page 46, lines 1-5), which is compressed in an algorithm known as Context Tree Weighting Method (page 43, abstract, lines 7-8). Matsumoto et al. also disclose other algorithms which expand DNA sequences in size (page 43, abstract, lines 6-7 and page 44, lines 29-31).

Fujimiya et al. state that previous conventional gene database retrieval systems require a large-scale computer having a capacity to perform large volumes of computations, but that such a computer system is not always readily available (col. 8, lines 46-53). Fujimiya et al. discuss the need to make highly accurate homology retrieval with practical processing time (col. 8, lines 56-60). Matsumoto et al. state that database sizes are increasing fast so that there is a need to store and communicate data efficiently (page 43, lines 4-6). Lincoln et al. state the need for a computer-based system to efficiently analyze and compare genetic sequences and corresponding biological data (col. 2, lines 43-47). A skilled artisan in the art would have been motivated to make improvements to a rapid homology retrieval program, such as that stated by Altschul et al. (page 403, abstract, line 1) on various datasets in order to provide faster and more accurate access of the information to users, as stated by Fujimiya et al. (col. 8, lines 46-53) and Matsumoto et al. (page 43, lines 4-6). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to test datasets, as stated by Anderson

et al. (page 350, col. 2, lines 48-50 and page 351, col. 1, lines and Table 1), containing possible

combinations as stated by Fujimiya et al. (col. 4, line 27 and col. 6, lines 24-26), by using a

homology retrieval BLAST program, as stated by Altschul et al. (page 403, abstract, line 1), and

speeding up the process by compressing files, as stated by Matsumoto et al.(page 43, abstract,

lines 7-8) and looping the sequences analyzed, as stated by Lincoln et al. (col. 12, lines 48-51),

with generated reports which could all be sent over a network of CPUs and databases in order to

allow greater, faster, and efficient access to users of the homology information via methods and a

computer system (Fujimiya et al., col. 8, lines 56-60 and Matsumoto et al., page 43, lines 4-6) at

the time of the invention . Thus, Altschul et al., in view of Fujimiya et al. (P/N 5,706,498),

Anderson et al. (1998), Lincoln et al. (P/N 6,303,297), and Matsumoto et al. (2000) motivate the

limitations of claims 1, 4, 6-7, 9-10, 12-13, 16, 18-21, and 23.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile

transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

in Crystal Mall 1. The faxing of such papers must conform with the notices published in the

Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either

(703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The

examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 3, 2003

ARDIN H. MARSCHEL
PRIMARY EXAMINER